State of Wisconsin
Department of Health Services

Jim Doyle, Governor
Karen E. Timberlake, Secretary

Senate Committee on Health
Tuesday, August 18, 2009

Wisconsin Department of Health Services
Rachel Currans-Sheehan, Legislative Liaison

Chairman Erpenbach, Senator Robson, and members of the Health Committee, thank you for the opportunity to present information on Wisconsin's Drug Repository Program.

The Wisconsin Drug Repository Program has been operating in Wisconsin for four years with 28 pharmacies volunteering to participate in this program.[1]

A recent survey of participating pharmacies found that in 2008, on average, a pharmacy received 9.75 donated prescriptions and dispensed approximately 5.83 of these prescriptions. Using these averages, it can be estimated that 163 prescriptions were dispensed through the Drug Repository Program in 2008.

The purpose of the drug repository is to provide access to medications for patients who have cancer or chronic diseases and valid prescriptions from their physicians, but do not have the means to pay for the medication. Pharmacies accept donated medications which meet specified qualifications, and dispense these medications to qualified persons who inquire at the pharmacy.[2]

Given that the statutory definition of "chronic disease" is fairly expansive, most pharmacies participating in the program accept many types of medications, excluding controlled substances or drugs on FDA-mandated restricted distribution programs.

The Department of Health Services implements the program by providing the guidelines for pharmacies, donors, and recipients' participation in the program.

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[1] There are approximately 1,100 pharmacies in the state of Wisconsin.
[2] Additional information on the Drug Repository Program can be found online at http://dhs.wisconsin.gov/bqaconsumer/cancerdrugreposy.htm.

The Department monitors pharmacies compliance with these guidelines and the FDA-mandated restricted distribution program.

A recent survey of participating pharmacists found that there are many tangible examples illustrating the benefits of the program.

- Patients are able to obtain access to medication they would not have access to otherwise,
- Donors are pleased to have a way to dispose of unused medications, and
- Participating pharmacies are connected to the community and have a means to help those that need essential medication.

While there are benefits to the program, DHS and pharmacies face barriers to operate a robust and efficient program.

- A recent survey of 15 participating pharmacies showed that up to half of drugs donated were either unused or disposed of.
- Recipients, pharmacists and donors lack knowledge of the program; the Department lacks resources to market the program.
- Wisconsin does not have a coordinated registry system which means participating pharmacies cannot search for medications and supplies available at other repository sites. The Department lacks resources to create a coordinated registry system.
- Pharmacists lack information on what to do with the disposal of unused drugs; this barrier is not unique to the drug repository program.
- Medications included in the repository program are most often excluded not because of the type of disease they treat (ie: cancer, chronic disease), but due to the requirement that medications must be in "original, unopened, sealed, and tamper–evident unit dose packaging or, if packaged in single–unit doses, the single–unit–dose packaging is unopened" and the expiration date must be 6 months from date of donation. It is more cost-efficient for pharmacies to package medications in prescription pill bottles than to package medications in tamper-evident unit dose packing.

SB 198 addresses the challenge that the pool of qualified medications is small due to "expiration date standards." Changing the expiration date standards from 6 months to 90 days will expand the number of medications eligible for the program because medications with expiration dates earlier than 6 months, but less than 90 days from date of donation will now be accepted in the program.

SB 198 expands the drug repository program to include additional medications by removing the type of disease ("cancer" and "chronic disease") to define accepted medications. This is laudable and will ease the public understanding of accepted

and available medications for donation to the program; however, the benefits may not be as far-reaching as intended without additional resources to implement a robust registry program.

Using existing resources, DHS will be able to provide guidance to pharmacists and providers on the expansion of the program through online provider updates and will work to expand the number of participating pharmacies. DHS' ability to market the program to a wider audience to ensure people are fully utilizing the program will remain limited without additional resources.

Thank you for the opportunity to testify today on SB 198. I would be happy to take any questions you may have.

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August 18, 2009

Testimony of Greg Chesmore, Director of State Government Relations
Supporting Senate Bill 198

Chairman Erpenbach and members of the Committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue, I'd like to thank you for the opportunity to share Celgene's support for SB 198.

As a multinational biopharmaceutical company, Celgene seeks to deliver truly innovative and life-changing drugs for our patients, specializing in products for the treatment of cancer and other severe, immune, inflammatory conditions. Specific to the legislation before this committee today, Celgene manufactures the anticancer drugs, Thalomid® (thalidomide) and Revlimid® (lenalidomide), an analog of thalidomide. Because both drugs are unique, extremely active compounds with the potential to cause severe birth defects, the drugs can only be obtained through restricted distribution programs mandated by the federal Food and Drug Administration (FDA).

Our Thalomid® product (through the FDA-approved "System for Thalidomide Education and Prescribing Safety" or S.T.E.P.S.® program) requires comprehensive counseling and regular pregnancy testing for women of child-bearing age, patient surveys and registration, physician-patient agreement forms, prescriber surveys and registration, and unique authorization numbers for each prescription---all of which must be completed before the drug can be dispensed. This program is in place to protect the patient and ensure safe delivery of these medications through contracted pharmacies. Celgene's Revlimid® product has a similar FDA-approved program in place, RevAssist®.

Today, Thalomid® and Revlimid® are two of the most commonly prescribed drugs for multiple myeloma. Thalomid® is not available at most pharmacies and Revlimid® is not stocked on commercial pharmacy shelves (the drug is commonly drop-shipped directly to patients). This limited distribution environment elevates the risk of pharmacists being unfamiliar with comprehensive restricted distribution programs like S.T.E.P.S.® and RevAssist®.

Without specific legislative language prohibiting the acceptance and redistribution of these drugs within state-run prescription drug repositories---like that which is properly included in SB 198---we are gravely concerned that individuals may access these medications outside of the federally-required restricted distribution process. Currently, Wisconsin's existing Cancer and Chronic Disease Repository does not have specific language in place to ensure that restricted distribution drugs like Thalomid® and Revlimid® are not donated and redistributed. While the Department of Health Services has been willing to take steps to provide information to participating pharmacies about these FDA restricted distribution programs, the

existing program lacks the statutory or regulatory language necessary to protect Wisconsin residents.

Upon learning of this issue and the risk for possible inadvertent exposure through access outside of the FDA-mandated process, many states---including Arizona, Colorado, Montana, Michigan, Kansas, Virginia, Pennsylvania and Nebraska---have specifically exempted these types of drugs from the state's programs dealing with utilization of unused prescription drugs.

In light of the worldwide tragedy that occurred several decades ago, it was once considered unthinkable that thalidomide would ever be marketed in the United States. Yet, Celgene has carefully researched and developed thalidomide as a safe and effective treatment for patients. The restricted distribution programs placed on drugs like Thalomid® and Revlimid® must be respected at all times.

The goal we all share is ensuring that patients have access to the drugs they need---and ensuring patient safety throughout the distribution process.

I applaud Sen. Robson and Rep. Nygren for their foresight in including this important, protective language in this legislation and urge you to support SB 198.

Thank you for your time and consideration.

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Developing Drug Repository Programs Raise Concerns, Boards of Pharmacy Contribute Expertise in Creation of Regulations

Increasing prescription costs continue to raise concerns for those struggling to purchase critical medications. As a possible solution, more states are considering implementation of drug donation or repository programs, which allow certain institutions, and in some cases individuals, to donate unused medications. These donated medications, if confirmed to be unopened, unexpired, and safe for patient use, may eventually be distributed to the medically indigent. Currently, 35 states allow drug repository programs to exist, according to the 2009 *Survey of Pharmacy Law.* Though some states have working programs today, many are still awaiting promulgation of rules in order to make them operational.

In December 2008, NABP surveyed the state boards of pharmacy about recycling unused medications and found that eight of the 19 boards that responded allow drug repository programs to exist or operate, while at least two are awaiting development of rules prior to implementation. The survey was conducted as a follow up to a February 2006 survey on this issue. Of those boards that responded to both the 2006 and the 2008 surveys, five did not allow for drug repository programs to exist or operate in 2006, but now have programs or laws in effect to do so. See the August 2006 *NABP Newsletter* article "State Boards' Donation Programs for Unused Prescription Medications Balance Patient Needs, Safety," for details on the results of the February 2006 survey.

In several states, the boards of pharmacy have worked closely with their state legislatures to develop regulations for these programs. In 2007, North Dakota Governor John Hoeven signed House Bill 1256 into law authorizing the state prescription drug repository program. While the program was developed at the request of the American Cancer Society, the North Dakota State Board of Pharmacy was responsible for developing the criteria for the establishment of the program and handling the registration of participants for the receipt and dispensing of the donated items.

Similar to North Dakota, the Pennsylvania State Board of Pharmacy, which specifically allows for a cancer drug repository program, and the Virginia Board of Pharmacy are responsible for promulgating regulations for their states' programs; however, according to the December 2008 survey, neither program is operational yet as both are still in the rule development and approval process.

Safety Concerns

As indicated above, state legislators will often implement drug repository programs and empower the boards of pharmacy to develop rules and oversee the programs. The boards' expertise in the distribution of safe and effective medications is a necessary component in the development of regulations for such programs as it ensures that the public health and safety remains the top priority. In fact, pharmaceutical manufacturers that produce drugs that must be distributed through restricted distribution programs, including isotretinoin and thalidomide, see the boards of pharmacy as integral to ensuring that all the proper safeguards are in place. According to one biopharmaceutical company representative, "while lawmakers usually exclude controlled substances from the donation programs, oftentimes other higher risk medications are not explicitly prohibited from donation and redistribution."

Food and Drug Administration (FDA) has implemented restricted distribution programs for approximately 15 different drugs that require registration with the manufacturer and patient education. In some cases, these requirements also include registration by the prescriber and dispenser. The number of medications that require special attention by manufacturers and, subsequently, state-run repository programs, is on the rise.

Several states, including Arizona, Colorado, Kansas, Michigan, and Virginia have explicitly excluded drugs for which FDA has required a restricted distribution program to be in place, notes the company representative. Effective this year, the Kansas State Board of Pharmacy promulgated KAR 68-18-2, which specifies that "a qualifying center or clinic shall not accept or dispense an unused medication that can be dispensed only to a patient or resident registered with the drug manufacturer." Regulations such as this one further assist in protecting the public health and safety. Without safeguards in place, some fear that the medication could be inadvertently redispensed to another patient outside of the FDA-mandated restricted distribution program.

As in Kansas, Arizona proposed rule R4-23-1203, Eligible Prescription Medications, which specifically states:

> A prescription medication may be donated to a physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program if the prescription medication . . . is not a . . . drug that can only be dispensed to a patient registered with the drug's manufacturer, because donation could

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Drug Donation Programs

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prevent the manufacturer from maintaining required patient registration data.

A few states such as Delaware, Oklahoma, and South Carolina permit, under limited circumstances, *pharmacists* to "return" or "reuse" medications, but specifically indicate that they do not allow for a drug repository or donation program to exist. According to Delaware regulation 5.11, products under the direct control of a health care professional, that are packaged in manufacturer unit dose or tamper-proof unopened bulk containers, with the tamper-proof seal intact, including unused multi-dose punch cards, may be redispensed in accordance with expiration dating in the customized patient medication package, but partially used products may not be redispensed. In addition, the regulation prevents medication that potentially has been diverted or adulterated, is not secure, or is expired from being placed back in the distribution system by prohibiting returns or exchanges by any pharmacist or pharmacy after having been taken from the premises where sold, distributed, or dispensed.

Likewise, the Oklahoma State Board of Pharmacy developed a program that, under limited circumstances, allows specific facilities to donate unused medications through its non-central repository program, the Unused Prescription Drug Program for Oklahoma's Medically Indigent. After conducting several trials, the Board developed rules for the program that allow Oklahoma licensed nursing homes, approved Oklahoma licensed assisted living centers, and licensed prescription drug manufacturers to donate unused medications for distribution to indigent patients as specified in OAC Title 535, Subchapter 12. The state has approximately 36 charitable clinics with pharmacies that are able to receive these unused prescription drugs. In addition to these pharmacies, county-operated pharmacies are allowed to receive and dispense the unused medications. According to the Tulsa County Medical Society, in Tulsa County, a total of 47,878 prescriptions have been filled from the time the program was implemented in November 2004 to February 2009, an average wholesale value of $4,894,000.

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Safeguarding Patient Safety: NABP to Explore Methods of Medication Repository Programs

Drug donation and repository programs have been implemented in several states; however, hesitations remain. Various factors contribute to these hesitations, including questions of how to ensure the efficacy and safety of a medication, how to regulate the medications and those distributing them, and how to assign liability in situations where medications have left the normal chain of distribution.

In December 2008, NABP convened the Task Force on Medication Collection Programs in Tucson, AZ, to discuss methods of medication collection and disposal. During this meeting the task force addressed reuse of medications and recommended that NABP work with the boards of pharmacy and appropriate state and federal agencies, such as Food and Drug Administration, to research programs for the reuse of previously dispensed medications. The focus of the research would be to ultimately determine whether safe and legally compliant methods can be utilized.

After reviewing several prescription medication repository programs currently in existence, task force members discussed the societal value of such programs and why medications should be reused instead of destroyed. They acknowledged that medications in long-term care facilities are maintained within a closed distribution system and, thus, may be appropriate for reuse. However, any programs in the community pharmacy setting would necessitate different requirements, as they raise questions about medications that have left the normal drug distribution channel and their likelihood of having been maintained in a controlled climate and monitored environment. The standards for these medications should be the same as the standards required of all other medications and must ensure that the medications dispensed are non-adulterated and non-misbranded.

Task force members also agreed that any medication collection programs for reuse must be compliant with all state and federal regulations, including standards of the United States Pharmacopeial Convention, to ensure public safety. The full task force report, which was approved by the NABP Executive Committee at its February 2009 meeting, is available on the NABP Web site at *www.nabp.net*, under News/Press.

The Iowa Prescription Drug Corporation (IPDC), which began operating its repository program in May 2007, voiced the importance of maintaining the quality and effectiveness of medications, stressing that patient safety is of utmost concern at all times as is ensuring in its program that "all [long-term care] medications are under the continuous control of a health care professional . . . verified by a licensed pharmacist for accuracy . . . [and] scrutinized for integrity and proper expiration dating."

Overseen by the Iowa Department of Public Health in cooperation with the Iowa Board of Pharmacy, the IPDC program was established to improve the health of low-income Iowans by authorizing medical facilities and pharmacies to redispense prescription drugs and supplies that would otherwise be destroyed. From March 2007 to December 2007, the repository received medication donations of almost 319,000 dosage units, valued at an estimated $292,000. During that same time period, almost 142,000 dosage units of medication, worth an estimated $150,000, were distributed through the program to indigent patients.

Handling Liability

Though patient safety is the primary concern with repository programs, the issue of liability has also been raised. Several states have included or are attempting to include language in their rules to address this subject. In the December 2008 survey on recycling unused medications, Paul Boisseau, immediate past executive secretary of the New Hampshire Board of Pharmacy, responded that "the Board is currently seeking additional legislation that would include pharmacies and pharmacists participating in a donation program to be covered under the existing Limited (liability) Immunization section of the law," which currently protects only manufacturers of the donated drugs.

According to Boisseau, the state will need to expand this language to make it applicable to pharmacies and pharmacists in order for the prescription drug program to be viable.

Iowa and South Carolina also address liability in their rules. The Iowa Administrative Code exempts drug manufacturers, as well as others such as pharmacists, acting in good faith, from criminal prosecution, civil liability, and disciplinary action for injury to or the death of an individual to whom a donated prescription drug is dispensed as directed in chapter 641—109.11(135M) Exemption from disciplinary action, civil liability and criminal prosecution. In addition, South Carolina Code of Laws specifies in its Cancer Drug Donation Program Act in part that

> A donor of a cancer drug or supplies, or a participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies . . . are immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to donating, accepting, distributing, or dispensing cancer drugs or supplies pursuant to this article.

Addressing liability issues is just one step in developing and implementing these repository programs. Various concerns remain regarding their ability to maintain and ensure the efficacy of donated medications, and most importantly, their ability to protect the patients who are receiving them.

Legal Briefs

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respond to the peculiar, if not arbitrary, expectations of the Board."

The appellate court concluded that the licensee complied with the spirit of the Board order and that the trial court erred in affirming the sanction. Thus, it reversed the trial court holding and remanded the matter back to the Board to vacate the original order.

Under circumstances that dictate potential reentry into practice under specified conditions, boards of pharmacy are encouraged to examine sanctions intended to ensure public protection, while affording disciplined licensees with an opportunity for reinstatement. However, boards are encouraged to carefully craft such reinstatement conditions to ensure a reasonable opportunity for compliance and parameters ascertainable by the board and future boards that may rule on reinstatement requests.

Sutton v State Board of Pharmacy, 2008 WL 5390466 (App Ct OH 2008)